## IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
vs. ZACHARY C. WILLIAMS,	)	NO. CR-10-0216-HE (01)
	)	
	)	
	)	
Defendant.	)	

## **ORDER**

Defendant Zachary C. Williams has been charged by indictment with conspiracy to distribute Fioricet, a controlled substance (Count I), conspiracy to deliver, distribute and dispense Fioricit by means of the internet (Count II), conspiracy to introduce misbranded prescription drugs (Fioricet, Soma and Tramadol) into interstate commerce (Count III), and distribution of Fioricet (Counts IV -VII). He has filed a motion to dismiss the indictment, asserting that the alleged conduct does not violate the Controlled Substances Act ("CSA"). 21 U.S.C. §§ 801-904. Defendant claims the allegations are insufficient to support the conspiracy and distribution charges in Counts I, II and IV-VII because Fioricet is not a controlled substance. He argues that Count III does not allege a crime as the drugs that allegedly were misbranded -- Fioricet, Soma and Tramadol – were dispensed pursuant to valid prescriptions and "under the auspices of the Ponca Nation-issued pharmacy license," defendant William's motion, p, 1 and thus were exempt from the labeling requirements of the Food, Drug and Cosmetic Act.

<sup>&</sup>lt;sup>1</sup>The indictment also includes a forfeiture count.

When determining the sufficiency of an indictment, the court asks "whether the allegations in the indictment, if true, are sufficient to establish a violation of the charged offense." <u>United States v. Pope</u>, 613 F.3d 1255, 1260 (10th Cir. 2010) (internal quotations omitted). Reviewing the indictment under that standard, the court conclude's defendant's motion should be denied.

Fioricet is a combination drug that contains a Schedule III controlled substance.<sup>2</sup> By regulation the Attorney General may "exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part" of Subchapter I of the CSA. 21 U.S.C. § 811(g). The parties agree that, by regulation, Fioricit has been designated an "exempted prescription product." 21 C.F.R. § 1308.32. The issue is the effect of that designation.

The regulation provides that "exempted prescription products" are exempted "from the application of sections 302 through 305, 307 through 309, and 1002 through 1004 of the Act (21 U.S.C. 822-825, 827-829, and 952-954) and §§ 1301.13, 1301.22, and §§ 1301.71 through 1301.76 of this chapter for administrative purposes only." 21 C.F.R. § 1308.32. The court agrees with defendant that Fioricet is exempt from certain registration, labeling, packaging, record-keeping and security requirements. However, the exemption is expressly limited – "for administrative purposes only." The regulation does not exempt the product

<sup>&</sup>lt;sup>2</sup>Fioricet contains butalbital, a derivative of barbituric acid. 21 U.S.C. § 812(c), Schedule III, Part (b)(1);see http://www.justice.gov/dea/pubs/scheduling.html.

<sup>&</sup>lt;sup>3</sup>The Attorney General delegated his powers under the CSA to the Drug Enforcement Agency. 28 C.F.R. § 0.100.

from the application of Part D -- Offenses and Penalties – of Subchapter I of the CSA (sections 401-422(a) of the Act). Consequently, Fioricit cannot be distributed legally unless it is delivered "by, or pursuant to the lawful order of, a practitioner," which includes a validly licensed pharmacy. 21 U.S.C. §§841(a); 802(10), (11), (21).

The Attorney General/DEA could have exempted Fioricet "from the application of all" of subchapter I of the CSA but did not. Fioricet remains a controlled substance despite being an exempted prescription product. Therefore, defendant's challenge to Counts I, II and IV-VII, based on his argument that "exempt controlled substances are not recognized as controlled substances by the Government," defendant's motion, p. 12, fails.

Defendant contends the remaining count (Count III) does not allege an offense because, while it is based on White Eagle RX not being properly licensed, the pharmacy was, in fact, licensed by the Ponca Tribe. However, for purposes of the motion to dismiss the court accepts as true the allegations in the indictment that White Eagle RX did not have a valid pharmacy license.

Accordingly, defendant Williams' motion to dismiss [Doc. #49] is **DENIED**.

## IT IS SO ORDERED.

Dated this 9th day of November, 2010.

JOÉ HEATON UNITED STATES DISTRICT JUDGE

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